UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,818	03/14/2002	Iqbal Grewal	146392002400	2744

25226 7590 09/02/2010

MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
09/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/099,818	GREWAL, IQBAL	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,19,32,33,37,38,40-47,50-52,58 and 59* is/are pending in the application.

4a) Of the above claim(s) *19,40-45,58 and 59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 32-33, 37-38, 46-47 and 50-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 05/24/2010, has been entered.

Claim 1 has been amended.

Claims 9-18, 20-31, 34-36, 39, 48-49 and 53-57 have been canceled.

Claims 1-8, 19, 32-33, 37-38, 40-47, 50-52 and 58-59 are pending.

Claims 19, 40-45 and 58-59 have been withdrawn from consideration as being directed to a non-elected invention or species. See 37 C.F.R. 1.142(b) and M.P.E.P. 821.03.

As pointed out previously, applicant's election of Group I and the species of a CD40-specific antibody and a CD20-specific antibody as well as multiple myeloma in the reply filed on 11/14/2005 has been acknowledged.

Also, consistent with the previous indication, claims 1-8, 32-33, 37-38, 46-47 and 50-52 are under consideration in this application as they read on CD40-specific antibodies and CD20-specific antibodies as the specific agents as well as the various neoplastic diseases claimed in the interest of compact prosecution.

2. The text of those sections of Title 35 USC not included in this Office Action can be found in a prior Action.

This Office Action will be in response to applicant's amendment, filed 05/04/2010.

The rejections of record can be found in the previous Office Actions, mailed 08/08/2008 and 04/03/2009.

3. Claims 1-8, 32-33, 37-38, 46-47 and 50-52 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-8, 32-33, 37-38, 46-47 and 50-52 are indefinite in the recitation of "wherein the neoplastic disease or disorder is rituximab resistant" because it is not clear what is the association between neoplastic diseases / disorder and rituximab resistance as well as the metes and bounds of said disease/disorders.

For example, while a particular neoplastic cell (e.g., see Example 1 of the instant specification) may be resistant to killing or treatment with rituximab, it is not clear that a neoplastic disease/disorder is necessarily resistant to rituximab.

Alternatively, while a particular neoplastic cell may not be resistant to treatment with rituximab, there may be a selection for resistant neoplastic cells upon treatment with rituximab over time.

In turn, there may be mixed populations of multiple myelomas, where certain subpopulations may be treatable with rituximab and some subpopulations may be resistant to treatment with rituximab.

One of ordinary skill in the art would not be apprised of the metes and bounds of the targeted "neoplastic diseases / disorders" at the time the invention was made. Therefore, the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-8, 32-33, 37-38, 46-47 and 50-52 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The specification as originally filed does not provide support for the invention as now claimed: "wherein the neoplastic disease or disorder is rituximab resistant".

Applicant's amendment, filed 05/24/2010, directs support for the newly added "limitation" to Example 1, particularly pages 45-46 of the specification.

Tumor Cell lines

Ramos EBV-negative Burkitt's lymphoma, HS Sultan EBV-positive plasmacytoma and IM9 EBV-positive multiple myeloma cell lines were purchased from American Type Culture Collection (Manassas, VA 20110). Rituxan resistant Ramos lymphoma cell line was established through exposing the Ramos lymphoma cell line to high doses of Rituxan (500ug/mouse IP, 3 times/week for 3 weeks) in a subcutaneous xenograft scid mouse.

Anti-tumor activity of a murine anti-CD40 antibody (S2C6 (SGN-14) International Publication No. W® 00/75348) and an anti-CD20 antibody (RITUXAN® brand product) on RITUXAN® brand resistant Ramos lymphoma in transplanted SCID mice. The results are presented in Figure 5. Tumor) volume in mice receiving a combination of anti-CD40 antibody and an anti-CD20 antibody was significantly reduced compared with each of control animals and animals receiving anti-CD20 or anti-CD40 antibody alone.

In contrast to the reliance of an experimental model system relying upon a Rituxan ressistn Ramos lymphoma cell line that had been established via high doses of Rituxan,
the claims broadly read on "wherein the neoplastic disease or disorder is rituximab resistant".

The instant claims now recite limitations which were not clearly disclosed in the priority applications as well as the specification as-filed, and would have changed the scope of the priority applications and do change the scope of the instant disclosure as-filed.

It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP § 2163.05.

Therefore, reliance upon the species of a particular Ramos cell line does not provide sufficient written description for "neoplastic diseases or disorders which are rituximab resistant", as currently claimed.

The specification as filed does not provide a written description or set forth the metes and bounds of this phrase. The specification does not provide blazemarks nor direction for the instant methods encompassing the above-mentioned "limitations" as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. § 112.

Applicant is required to cancel the new matter in the response to this Office Action

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02 and 2163.06

6. Upon reconsideration of the amended claims, filed 05/24/2010, to recite "wherein the neoplastic disease or disorder is rituximab resistant",
the previous rejection under 35 U.S.C. § 103(a) has been withdrawn.

7. No claims are allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/
Primary Examiner
Technology Center 1600
Art Unit 1644
August 30, 2010